

### **STATUS OF CLAIMS**

Claims 1-104 are pending in the application. Claims 1-72 were withdrawn pursuant to an election requirement. Thus, Claims 73-104 are presented for examination.

### **REMARKS**

#### **Continued Examination Under 37 CFR 1.1114 and Request for Withdrawal of First Action Final**

It is respectfully submitted that the Examiner's issuance of a First Action Final does not take into account the substantial amendments made to independent Claims 73 and 87 in the previous Amendment and Response. Withdrawal of the finality of the action is requested.

#### **Withdrawal of Rejection Under 35 U.S.C. § 112, second paragraph**

Applicants acknowledges with thanks the withdrawal of the rejection of Claims 96, 98, and 99 under 35 U.S.C. § 112.

#### **Withdrawal of Rejection Under 35 U.S.C. §103(a)**

Applicants acknowledges with thanks the withdrawal of the rejection of Claims 80, 81 and 86 based on Bucay-Couto et al. U.S. Publication No. 2003/0018306.

#### **Rejection Under 35 U.S.C. § 102(a)/(e) – MODAK**

The Examiner rejects Claims 73-75, 80, 89, 95-97 and 103 under 35 U.S.C. § 102(a) or (e) as being anticipated by Modak et al. (U.S. Pat. No. 6,224,579) ("MODAK"). Applicants respectfully traverse these rejections.

For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978) (emphasis added). MODAK does not meet this standard.

MODAK does not teach each and every element of the claimed invention. More specifically, MODAK fails to teach all of the elements of the present invention as claimed in amended independent Claim 73, which is directed to:

a stent comprising a polymeric tubular shaft having more than one layer, said polymeric tubular shaft comprising a first annular layer comprising a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor, *a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer.* (emphasis added).

More particularly, MODAK does not teach either a first or a second barrier layer that at least partially covers an exterior and interior surface, respectively of a first annular layer. Indeed, the words “barrier” or “barrier layer” do not appear anywhere in MODAK.

In the most recent Office Action, the Examiner has failed to cite any portion of MODAK which describes such barrier layers. Instead, the Examiner mistakenly refers to layers in MODAK which contain active ingredients and that are applied by a dip coating process as barrier layers when, in fact, these layers contain active ingredients rather than being barrier layers. Specifically, MODAK uses a treatment solution with chlorinated phenols in combination with one or more silver compounds (col. 2, lines 47-52) and provides:

*Medical articles prepared according to the invention may be treated on their external surface, internal surface, or both. For example, and not by way of limitation, where the medical article is a catheter, the internal surface and/or external surface of the catheter may be treated according to the invention. For example, where it is desired to treat both internal and external surfaces, an open-ended catheter may be placed in a treatment solution such that the treatment solution fills the catheter lumen. If only the external surface is to come in contact with treatment solution, the ends of the catheter may be sealed before it is placed in the treatment solution. If only the internal surface is to come in contact with treatment solution, the solution may be allowed to pass through and fill the lumen but the catheter is not immersed in the treatment solution.* (MODAK, col. 5, lines 32-47, emphasis added)

MODAK also fails to teach all of the elements of the present invention as claimed in amended independent Claim 87, which is directed to:

a ureteral stent comprising a polymeric tubular shaft that is between 0.2 mm and 0.8 mm in wall thickness, said polymeric tubular shaft having more than one layer and comprising a first annular layer comprising (a) polymeric species consisting essentially of ethylene vinyl acetate copolymer and (b) antimicrobial species consisting essentially of triclosan;  
*a first polymeric barrier layer at least partially covering an interior surface of said first annular layer;*  
*and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer.* (emphasis added).

Again, as noted above for Claim 73, the Examiner mistakenly refers to layers that are applied by a dip coating process as barrier layers when, in fact, these layers of MODAK contain active ingredients rather than being barrier layers.

In addition to failing to teach all of the claimed elements, MODAK fails to teach the overall stent structure as it is presently claimed. The current invention is directed to an annular layer in the middle, with outer barrier layers such that at least a part of the interior surface of the annular layer is covered with a first barrier layer and at least a part of the exterior surface of the annular layer is covered with a second barrier layer. MODAK simply does not teach this type of multi-layered structure.

The Examiner's rejection of Claims 75, 80, 89, and 97-99 is similarly traversed for the reasons described above.

Thus, the rejections under MODAK under §102 should be withdrawn.

#### **Rejection Under 35 U.S.C. §102(e)/103(a) Based on MODAK**

Claims 84 and 90 are rejected under 35 U.S.C. §102(a)/(e) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over MODAK. The rejections under §102(a)/(e) are traversed for the reasons explained above for Claims 73 and 87. The rejection under §103(a) is traversed since MODAK by itself does not teach or suggest each of the elements of the claimed invention and the Examiner has not combined MODAK with any other reference for this rejection to cure the deficiencies of MODAK.

#### **Rejections Under 35 U.S.C. §103(a) Based on MODAK, SCHWARZ, BUSCEMI and FALK**

Claims 81-88 and 94 are rejected under 35 U.S.C. §103(a) as being obvious over MODAK. The rejection under §103(a) is traversed since MODAK by itself does not teach or suggest each of the elements of the claimed invention as noted above for Claims 73, 87, 84 and 90 and the Examiner has not combined MODAK with any other reference for this rejection. The additional limitations described in Claims 81, 82, 83 and 88 do not overcome the deficiencies in MODAK.

Claims 76-79 and 91-93 are rejected under 35 U.S.C. §103(a) as being unpatentable over MODAK in view of Schwarz et al. (U.S. Publication No. 2001/0022988) (“SCHWARZ”). This rejection is traversed for the reasons described above for Claims 73 and 87. SCHWARZ is cited to provide a teaching of ethylene vinyl acetate copolymer, but SCHWARZ is directed to completely different coating methods including, e.g., ionization deposition, plasma treatment and grafting as noted in paragraphs 51-52 of SCHWARZ. Such coating methods are not combinable with the dip techniques described in MODAK and SCHWARZ is not combinable with MODAK.

Claims 100-101 are rejected under 35 U.S.C. §103(a) as being unpatentable over MODAK in view of Buscemi et al (U.S. Patent No. 5,693,034) (“BUSCEMI”). This rejection is traversed for the reasons described above for Claims 73 and 87. In addition, BUSCEMI is directed to hydrogels which is subject matter that has no relevance to the present invention.

Claims 102 and 104 are rejected under 35 U.S.C. §103(a) as being unpatentable over MODAK in view of SCHWARZ and further in view of Falk et al. (U.S. Patent No. 6,048,844) (“FALK”), with the citation of FALK being limited to the use of ketorolac as an anti-inflammatory agent. This rejection is traversed for the reasons described above for Claims 73 and 87 and of claims 76-79 and 91-93 with respect to MODAK in view of SCHWARZ. The citation of FALK does not overcome the deficiencies of MODAK and SCHWARZ.

Thus, it is believed that the Examiner has not met his burden of establishing a *prima facie* case of obviousness which requires 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) a reasonable expectation of success; and 3) a teaching or suggestion of all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. (See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Thus, the rejections under §103(a) should be withdrawn.

## CONCLUSION

Applicants submit that Claims 73-104 are in condition for allowance, early notification of which is earnestly solicited. It is believed that this Response is being submitted in time for an

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Examiner Thomas Sweet

Advisory Action should the Examiner require further changes to the Claims. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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